K113656

JUL 26 2012

SECTION 5

510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS FOR CareGuide™ Oximeter

Submitter Information

Name:	Reflectance Medical, Inc. (RMI)
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Registration Number:	NA (RMI will apply for registration number following 510(k) clearance, prior to commencement of commercial shipment.)
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Date Prepared:	July 26, 2012

Device Name

Device Trade Name:	CareGuide™ Oximeter
Device Common Name:	Oximeter
Classification:	Sec 870.2700 Oximeter
Product Code:	MUD
Classification Panel:	Cardiovascular Device Panel

Predicate Devices

Device Trade Name:	Invos™ Somatic Oximeter
Device Common Name:	Oximeter
Classification:	Sec 870.2700 Oximeter
510(k) Number:	K051274
Product Code:	MUD

Device Trade Name:	Hutchinson InSpectra™ StO_2 Monitor
Device Common Name:	Oximeter
Classification:	Sec 870.2700 Oximeter
510(k) Number:	K012759
Product Code:	MUD

Device Trade Name:	Hutchinson SpotCheck™ StO_2 Monitor
Device Common Name:	Oximeter
Classification:	Sec 870.2700 Oximeter
510(k) Number:	K103613
Product Code:	MUD

Device Trade Name:	Spectros T-Stat™ Oximeter
Device Common Name:	Oximeter
Classification:	Sec 870.2700 Oximeter
510(k) Number:	K040684
Product Code:	MUD

Device Description

The CareGuide sensor uses Near Infrared Spectroscopy (NIRS) to calculate muscle oxygen saturation (SmO_2).

Characteristics	**Reflectance Medical CareGuide Oximeter**
Principle of Operation	NIR spectroscopy
Components	Monitor with reusable sensor and disposable pad
Light Source	LEDs
Parameters Measured	Tissue oxygen saturation (SmO_2)

The CareGuide Display is an all-in-one touch screen off-the-shelf computer. The display contains the user interface software, the algorithms that calculate SmO_2 from collected spectra, displays the current SmO_2 result and trends previous results. The CareGuide reusable sensor contains the optical and electronic elements necessary to collect spectra from skin, fat and muscle. The sensor has a 3m long cord with a USB connection to the CareGuide display. The sensor contains 3 major components: (1) light sources to illuminate the skin; (2) a spectroscopic detector to analyze the reflected spectra back from the subject and (3) a microprocessor to

control the optical components. The CareGuide Ray is a disposable sleeve which isolates the sensor optical elements from the patient's skin.

Indications for Use

The CareGuide™ Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The CareGuide displays the most recent value of SmO2, as well as a graphical trend of previous SmO2 measurements. The CareGuide System should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the CareGuide™ Oximeter has not been demonstrated in disease states.

Rationale for Substantial Equivalence

The CareGuide™ Oximeter is substantially equivalent to the Somanetics Invos™ Somatic Oximeter (K051274), the Hutchinson InSpectra™ StO_2 Monitor (K012759) and the Hutchinson Spot Check StO_2 Monitor (K103613).

The CareGuide Oximeter is substantially equivalent to the predicates by intended use and design.

- The principle of operation of the CareGuide Oximeter is identical to that of the predicate devices. They all use NIR Spectroscopy to measure tissue oxygen saturation.
- The CareGuide Oximeter is identical to the predicates in components. All devices have a Monitor with a Sensor.
- The CareGuide Oximeter has the same underlying LED light source as the predicates, with the similar ranges of wavelength (700-900 nm between the three devices).
- The CareGuide Oximeter and the predicates all display output as a numeric trend.
- The Intended Use is identical to the predicates. They are all intended for use as oximeters, to measure tissue oxygen saturation.

Further, the CareGuide Oximeter has multiple number of wavelengths like the T-Stat predicate Oximeter

Summary of Safety and Effectiveness Data

Testing demonstrates that the CareGuide Oximeter is a safe and effective oximeter meeting all relevant consensus and FDA recognized standards. The test results in this submission demonstrate that the CareGuide Oximeter meets the expected performance requirements for an Oximeter, and is therefore equivalent to the predicates relative to safety and mechanical properties. The accuracy of the CareGuide Oximeter against the gold reference standard of a

laboratory co-oximeter was demonstrated in an isolated perfused animal limb GLP study. The ability of the CareGuide Oximeter to measure tissue oxygen saturation in subjects with different skin color (pigmentation) has been demonstrated in the clinical environment.

Conclusion

The CareGuide Oximeter is equivalent to predicate devices in terms of technology (NIR Spectroscopy) and intended use. The CareGuide Oximeter, with its multiple source configuration to overcome the effect of skin pigmentation, does not raise new questions of safety or effectiveness, as compared to the predicates. Therefore, the CareGuide Oximeter is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 26 2012

Reflectance Medical, Inc.
c/o Nandini Murthy
Rgulatory Consultant, RMI
116 Flanders Road, Suite 100
Westborough, MA 01581

Re: K113656
Trade/Device Name: CareGuide Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter, tissue saturation
Regulatory Class: Class II (two)
Product Code: MUD
Dated: July 20, 2012
Received: July 23, 2012

Dear Ms. Murthy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): K113656

Device Name: CareGuide™ Oximeter

Indications for Use:

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Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K113650